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**Sheldon et al.**

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(45) **Date of Patent: *Aug. 23, 2016**

(54) **SYSTEMS AND METHODS FOR ACCESSING THE LUMEN OF A VESSEL**

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This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**

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**Related U.S. Application Data**

(62) Division of application No. 13/080,318, filed on Apr. 5, 2011, now Pat. No. 8,945,011.

(51) **Int. Cl.**
***A61B 8/08*** (2006.01)
***A61B 8/00*** (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ..... ***A61B 8/0841*** (2013.01); ***A61B 5/14*** (2013.01); ***A61B 5/15003*** (2013.01); ***A61B 5/153*** (2013.01); ***A61B 5/150748*** (2013.01); ***A61B 8/14*** (2013.01); ***A61B 8/4209*** (2013.01); ***A61B 8/4444*** (2013.01); ***A61B 8/463*** (2013.01); ***A61B 8/587*** (2013.01); ***A61B 17/3403*** (2013.01);
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(58) **Field of Classification Search**
CPC ..... A61B 17/3403; A61B 19/201; A61B 2017/3407; A61B 2017/3413; A61B 2019/5276; A61B 5/14; A61B 5/15003; A61B 5/150748; A61B 5/153; A61B 8/0841; A61B 8/0891; A61B 8/14; A61B 8/4209; A61B 8/4444; A61B 8/461; A61B 8/463; A61B 8/587; A61M 2005/1585; A61M 2005/1588; A61M 2025/0166; A61M 25/0105; A61M 25/0108; A61M 25/0111; A61M 25/0113; A61M 25/0606; A61M 25/065; A61M 25/09; A61M 25/09041; A61M 5/158; A61M 5/46
See application file for complete search history.

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*Primary Examiner* — Michael Rozanski
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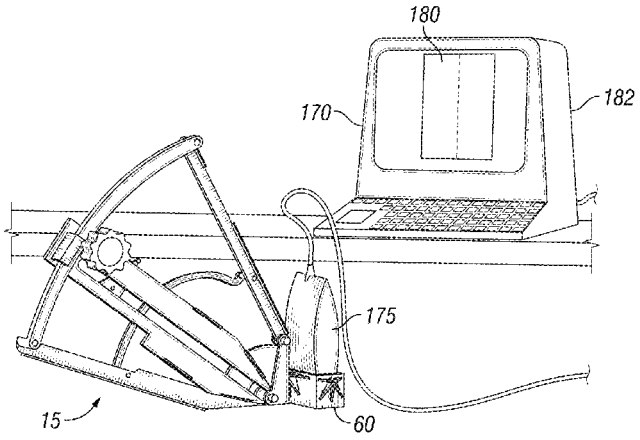
(57) **ABSTRACT**

A method for accessing the lumen of a vessel may utilize a reusable handheld device. The reusable handheld device includes an imaging device attachment utilized to secure an image capturing instrument, an arm coupled to the imaging device attachment, and a depth scale coupled to the arm, wherein the depth scale provides a scale indicating an insertion depth. A disposable cartridge attaches to the reusable handheld device. The disposable cartridge includes a sheath, needle or guidewire coupled to the disposable cartridge. The sheath or needle extends to the insertion depth when fully advanced, thereby allowing the sheath, needle, or guidewire to access the lumen of a vessel.

**24 Claims, 12 Drawing Sheets**



(51) **Int. Cl.**

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|---|---|
| ***A61M 25/09*** | (2006.01) |
| ***A61B 19/00*** | (2006.01) |
| ***A61M 25/01*** | (2006.01) |
| ***A61B 17/34*** | (2006.01) |
| ***A61B 5/15*** | (2006.01) |
| ***A61B 5/153*** | (2006.01) |
| ***A61M 5/46*** | (2006.01) |
| ***A61B 8/14*** | (2006.01) |
| ***A61B 5/145*** | (2006.01) |
| *A61M 25/06* | (2006.01) |
| *A61M 5/158* | (2006.01) |

(52) **U.S. Cl.**

CPC ..... ***A61B 19/201*** (2013.01); ***A61M 5/46*** (2013.01); ***A61M 25/0108*** (2013.01); ***A61M 25/0606*** (2013.01); ***A61M 25/09*** (2013.01); *A61B 8/0891* (2013.01); *A61B 8/461* (2013.01); *A61B 2017/3407* (2013.01); *A61B 2017/3413* (2013.01); *A61B 2019/5276* (2013.01); *A61M 5/158* (2013.01); *A61M 25/0111* (2013.01); *A61M 25/0113* (2013.01); *A61M 25/065* (2013.01); *A61M 25/09041* (2013.01); *A61M 2005/1585* (2013.01); *A61M 2005/1588* (2013.01); *A61M 2025/0166* (2013.01)

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| 2015/0087992 | A1 * | 3/2015 | Sheldon | A61B 17/3403 600/461 |

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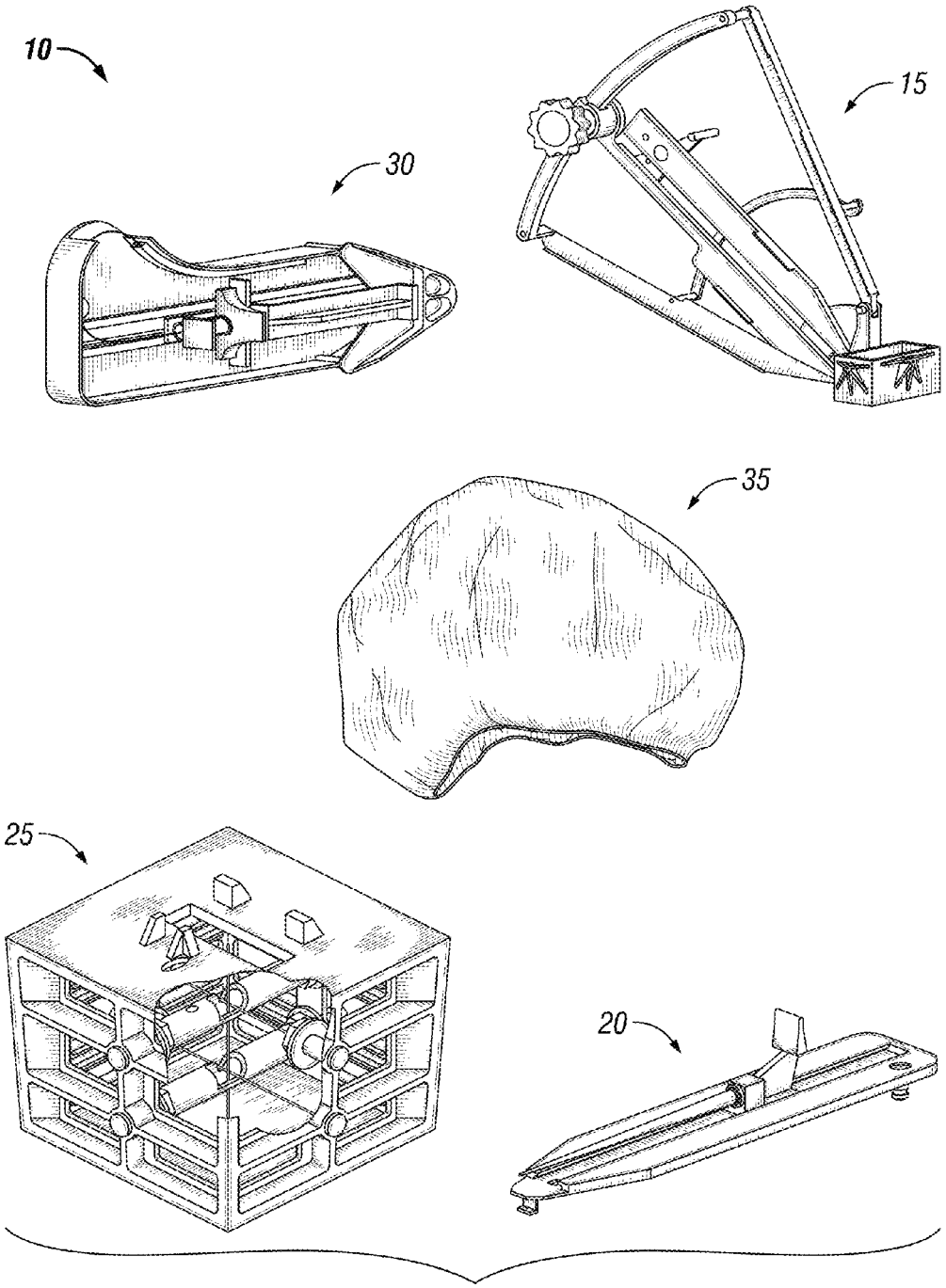



FIG. 1

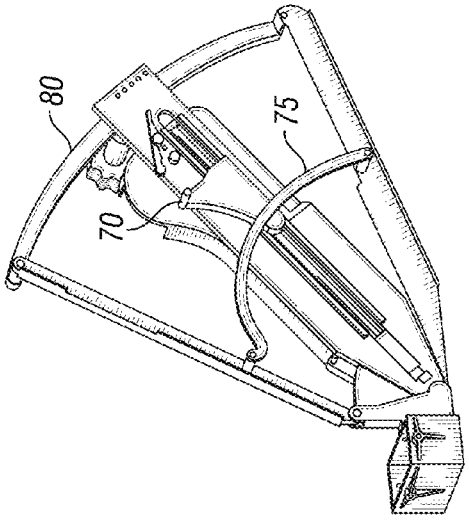



FIG. 2B

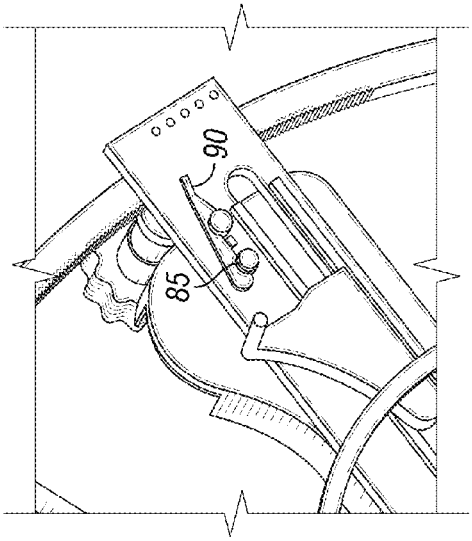



FIG. 3B

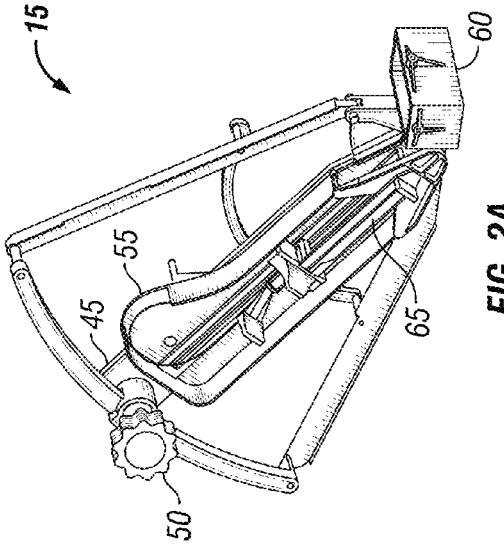



FIG. 2A

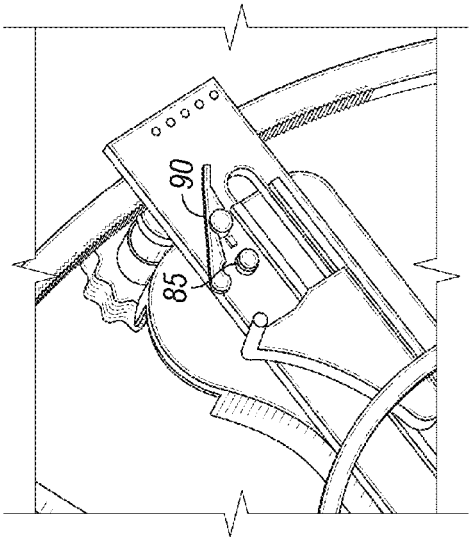



FIG. 3A

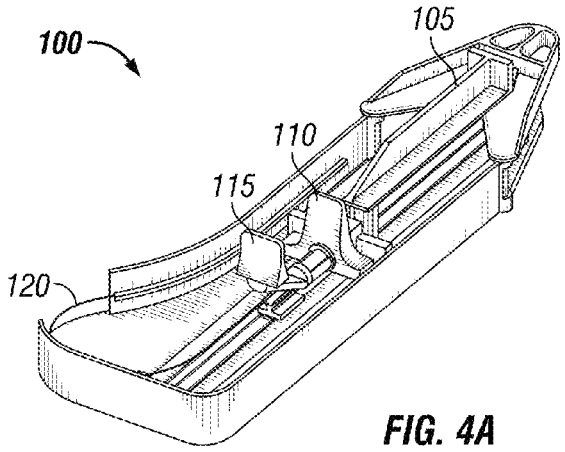



FIG. 4A

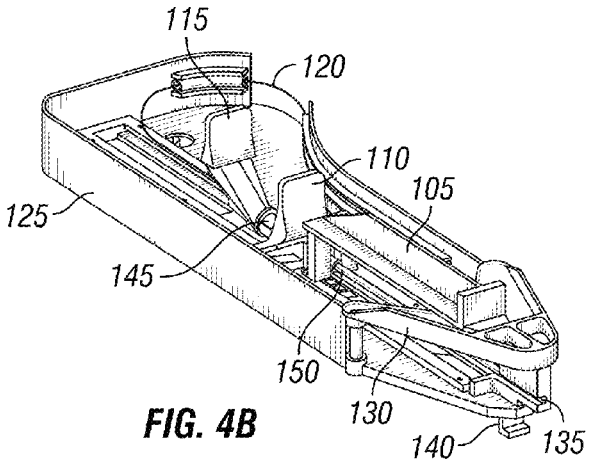



FIG. 4B

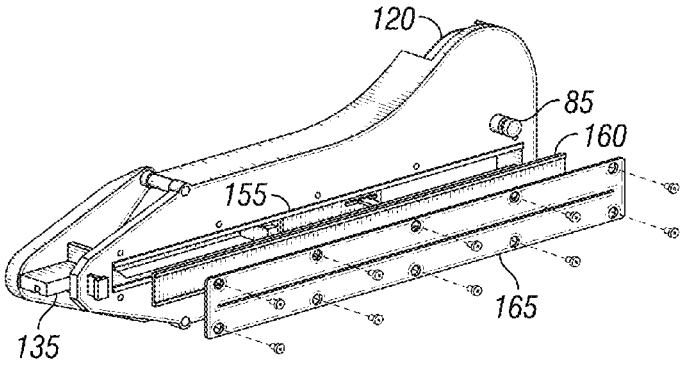
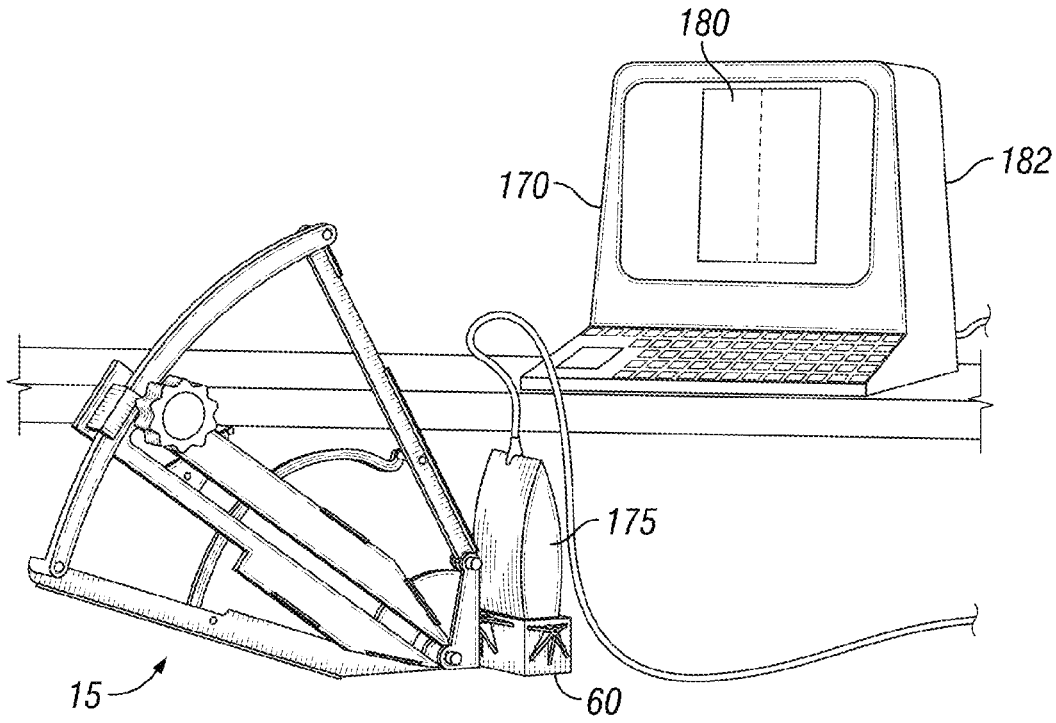



FIG. 5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182
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175
15
60

FIG. 6

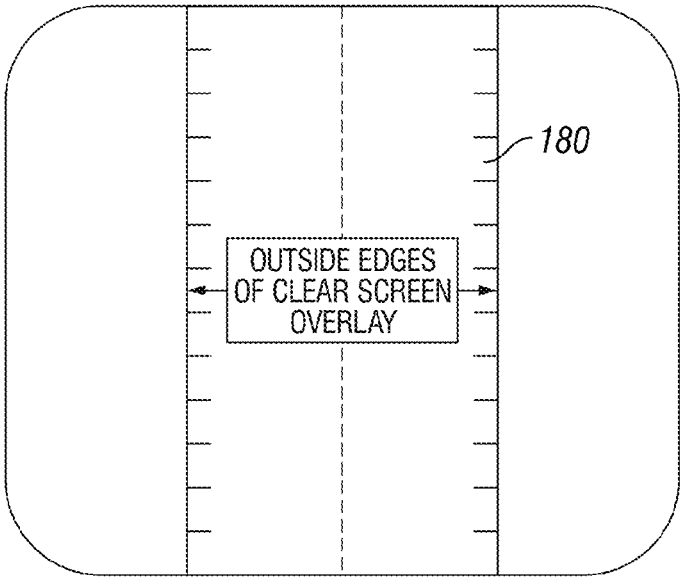

180
OUTSIDE EDGES
OF CLEAR SCREEN
OVERLAY

FIG. 7

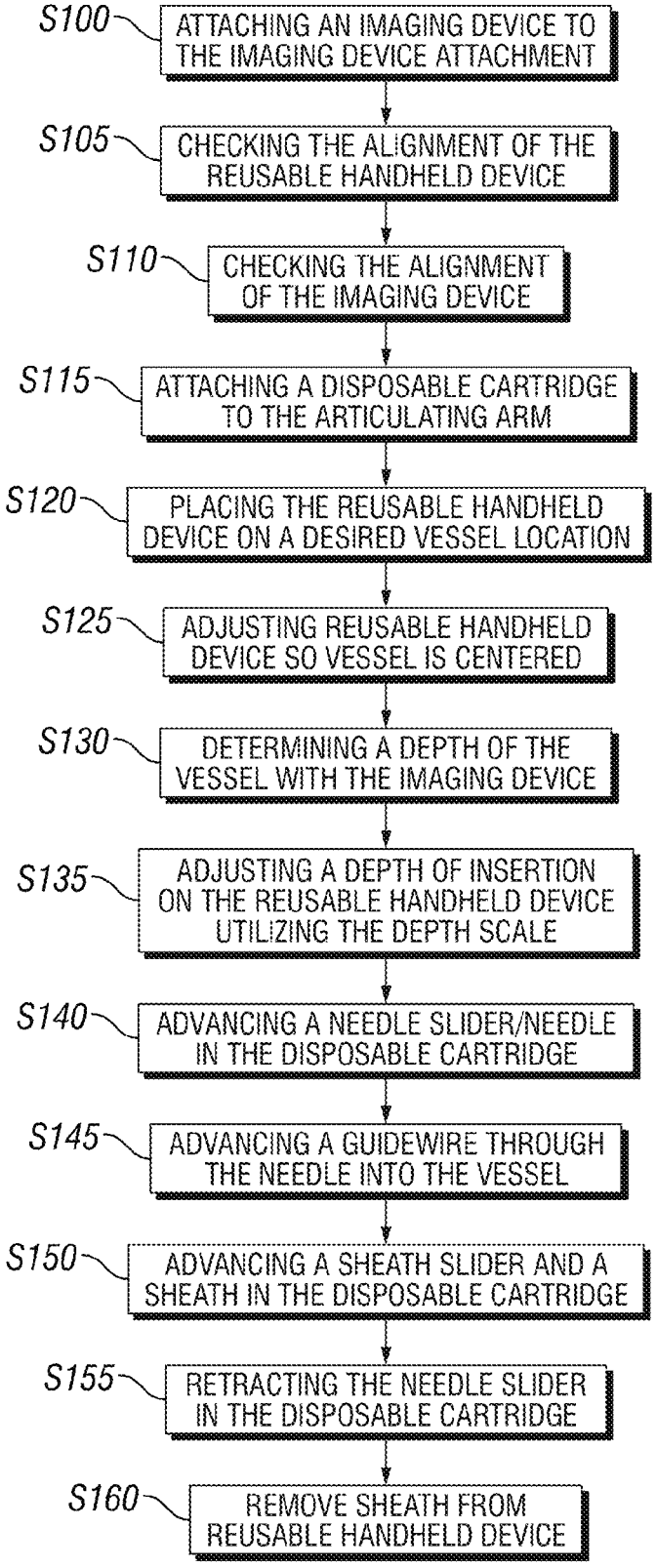
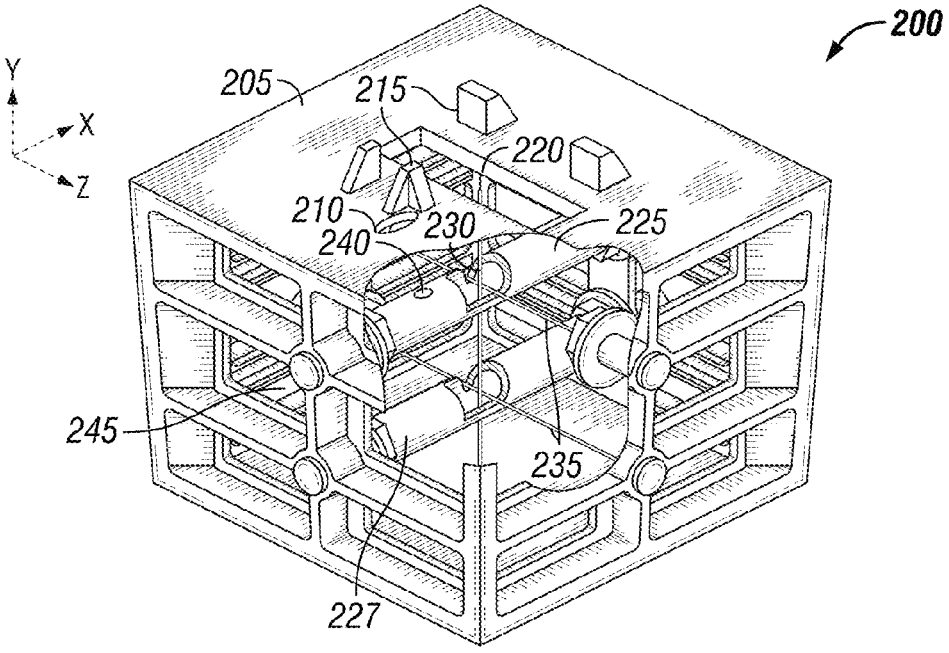

S100
ATTACHING AN IMAGING DEVICE TO THE IMAGING DEVICE ATTACHMENT
S105
CHECKING THE ALIGNMENT OF THE REUSABLE HANDHELD DEVICE
S110
CHECKING THE ALIGNMENT OF THE IMAGING DEVICE
S115
ATTACHING A DISPOSABLE CARTRIDGE TO THE ARTICULATING ARM
S120
PLACING THE REUSABLE HANDHELD DEVICE ON A DESIRED VESSEL LOCATION
S125
ADJUSTING REUSABLE HANDHELD DEVICE SO VESSEL IS CENTERED
S130
DETERMINING A DEPTH OF THE VESSEL WITH THE IMAGING DEVICE
S135
ADJUSTING A DEPTH OF INSERTION ON THE REUSABLE HANDHELD DEVICE UTILIZING THE DEPTH SCALE
S140
ADVANCING A NEEDLE SLIDER/NEEDLE IN THE DISPOSABLE CARTRIDGE
S145
ADVANCING A GUIDEWIRE THROUGH THE NEEDLE INTO THE VESSEL
S150
ADVANCING A SHEATH SLIDER AND A SHEATH IN THE DISPOSABLE CARTRIDGE
S155
RETRACTING THE NEEDLE SLIDER IN THE DISPOSABLE CARTRIDGE
S160
REMOVE SHEATH FROM REUSABLE HANDHELD DEVICE

*FIG. 8*


200
Y
X
Z
205
215
220
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230
225
240
245
235
227

FIG. 9

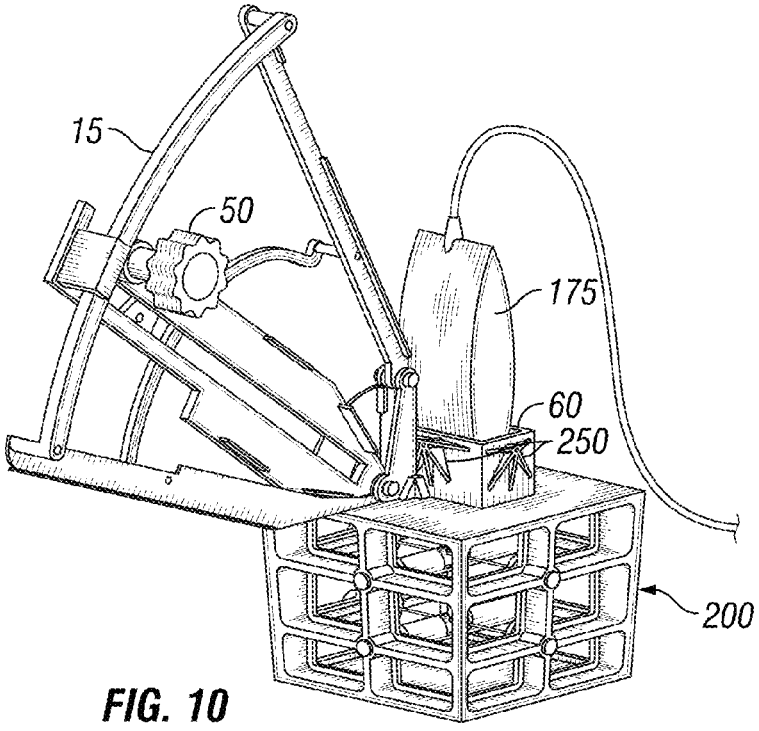
15
50
175
60
250
200

FIG. 10

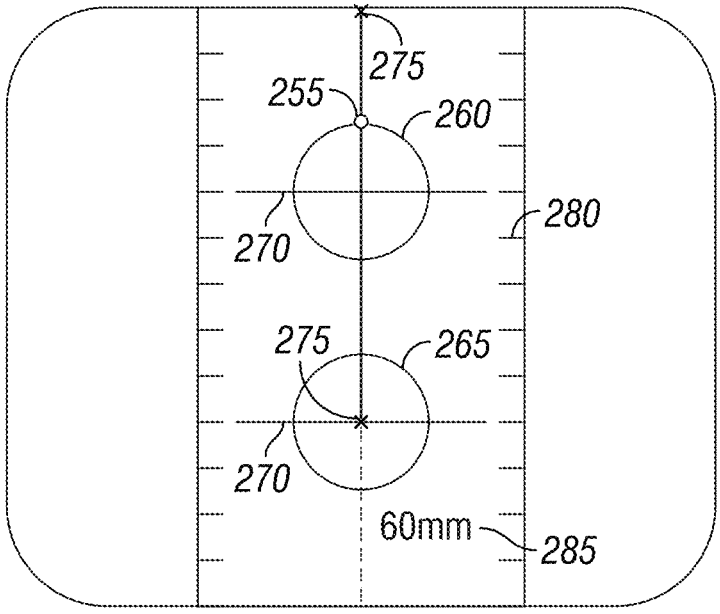


FIG. 11

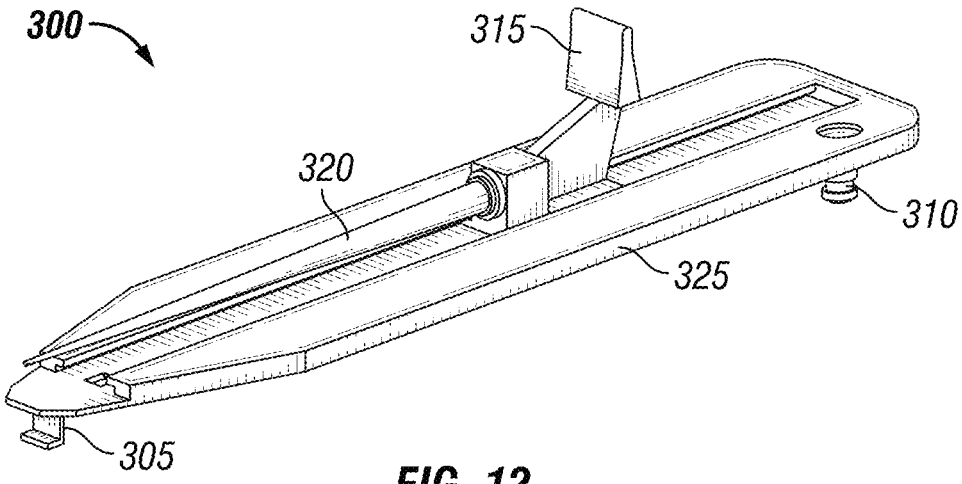


FIG. 12

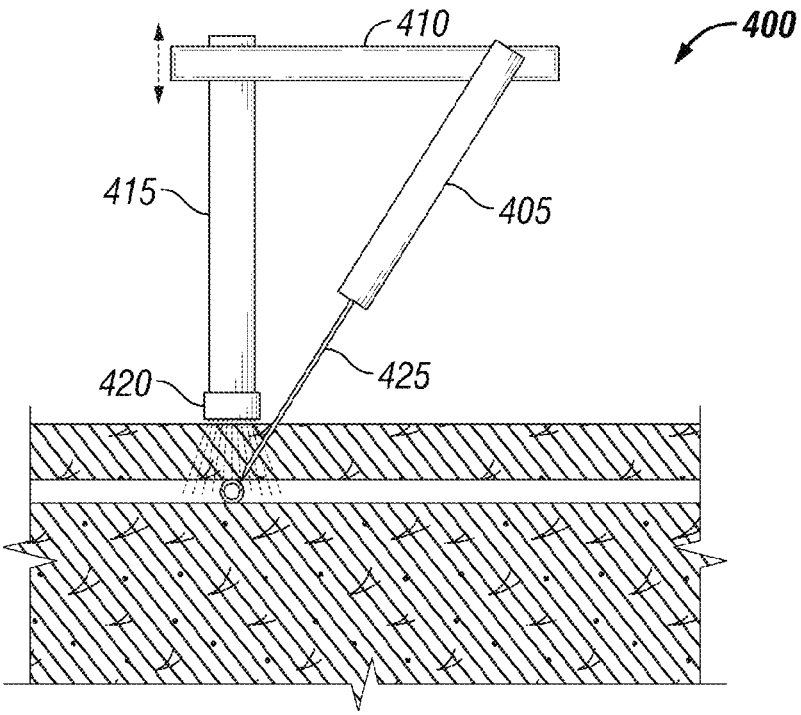


FIG. 13A

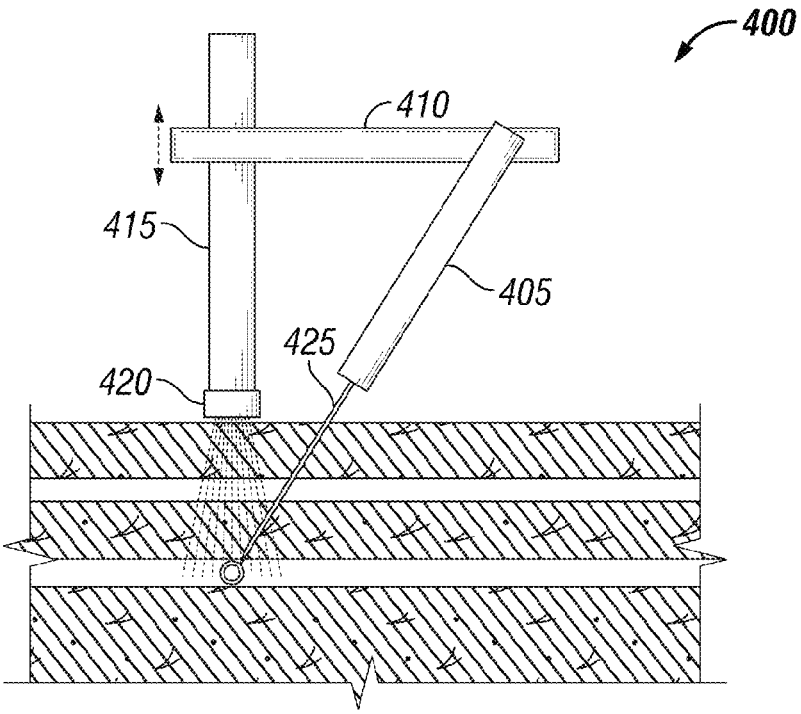


FIG. 13B

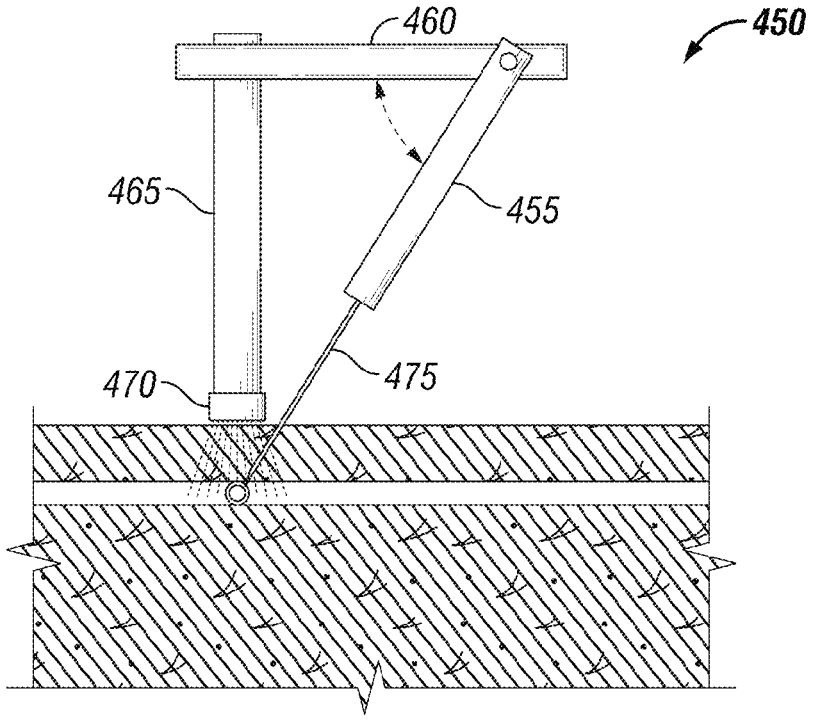


FIG. 14A

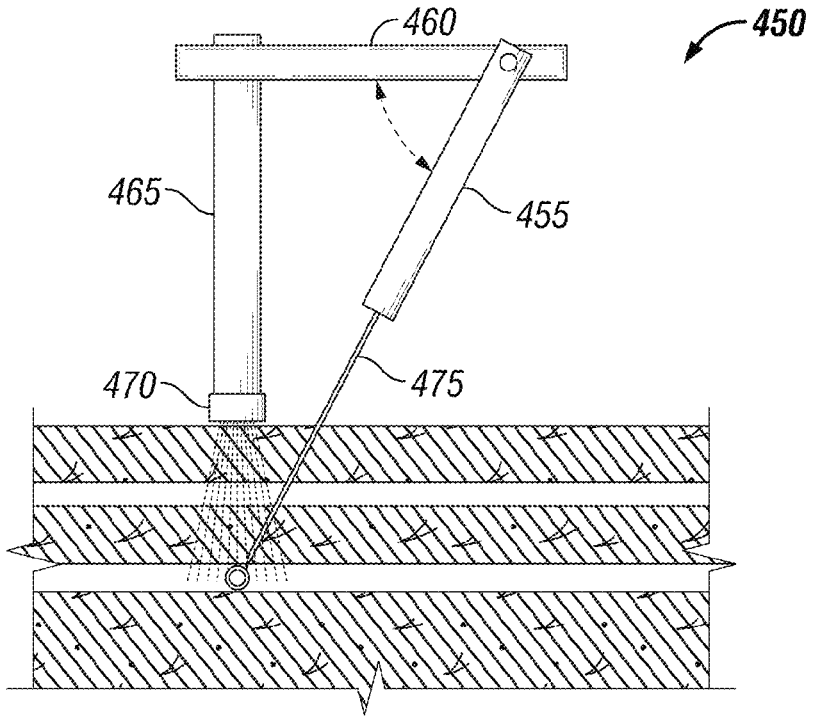


FIG. 14B

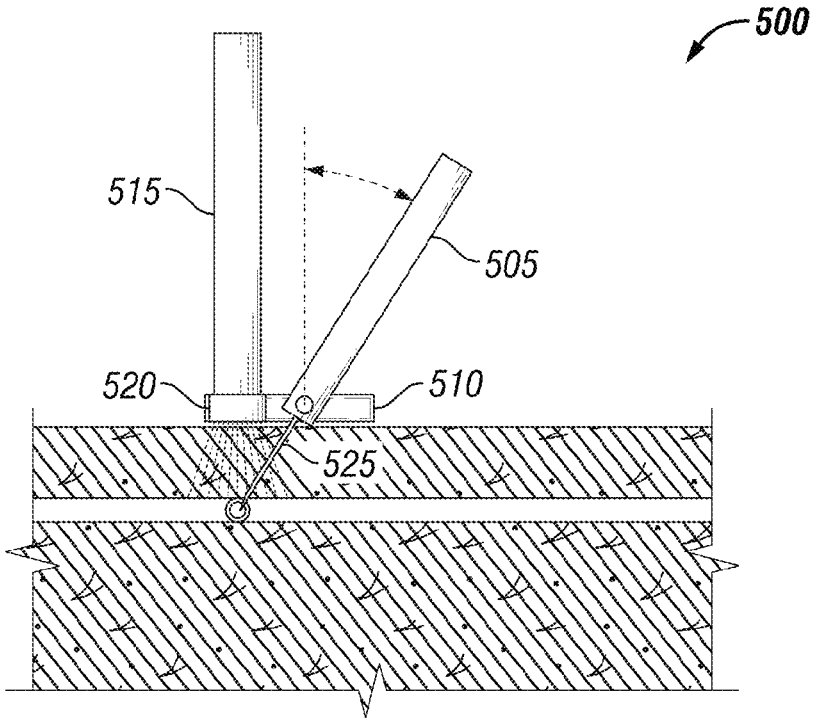


FIG. 15A

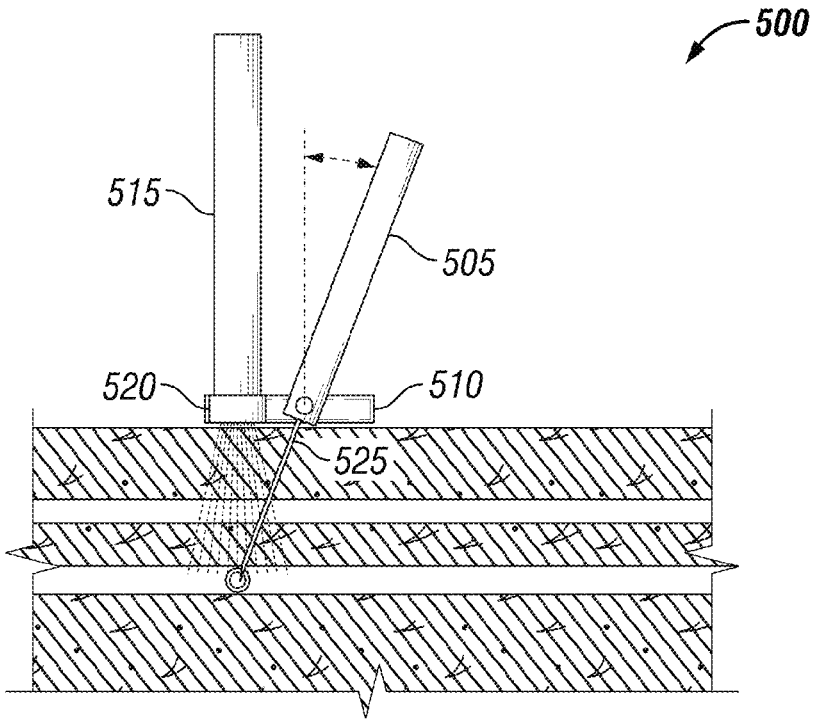


FIG. 15B

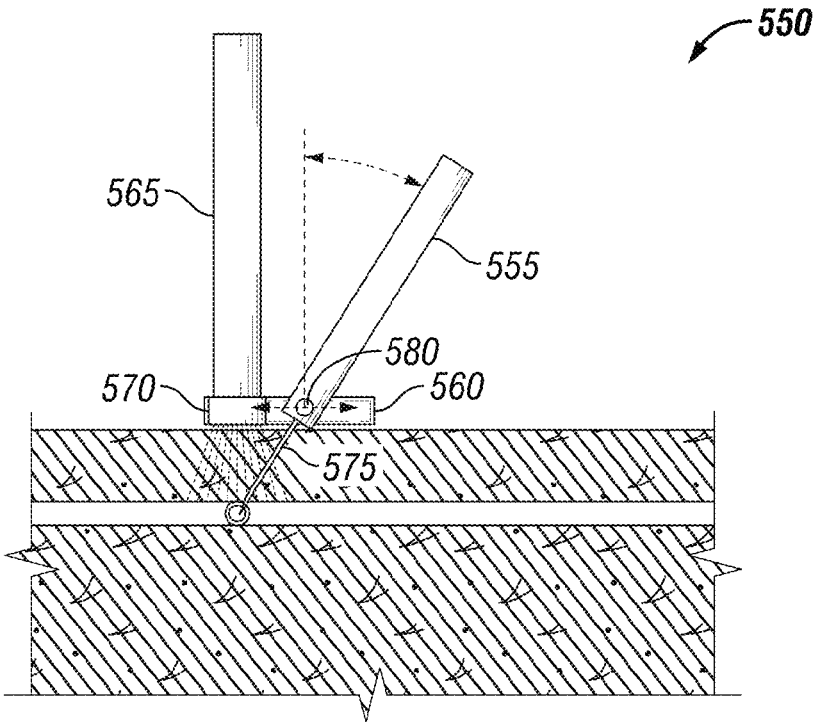


FIG. 16A

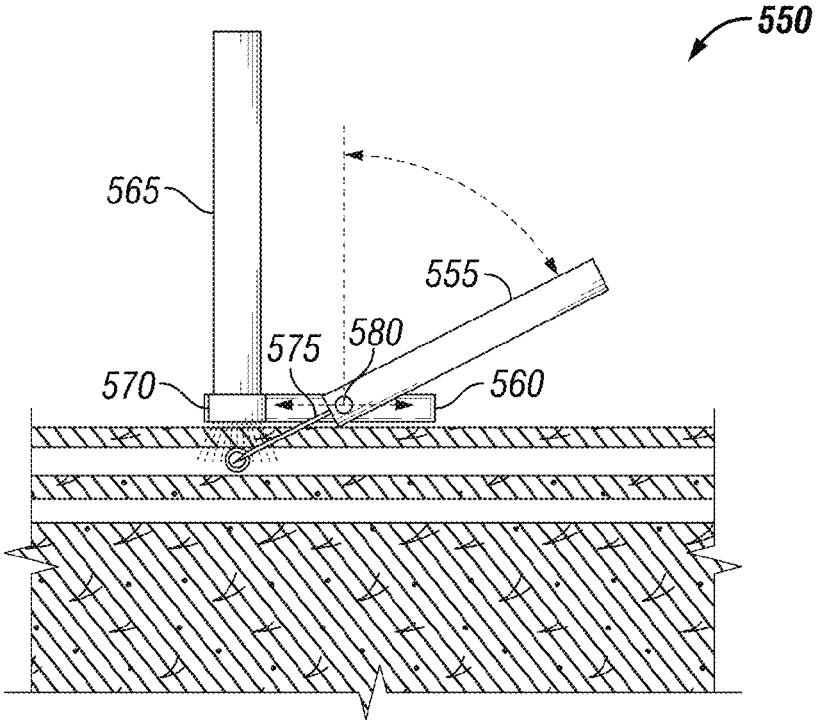


FIG. 16B

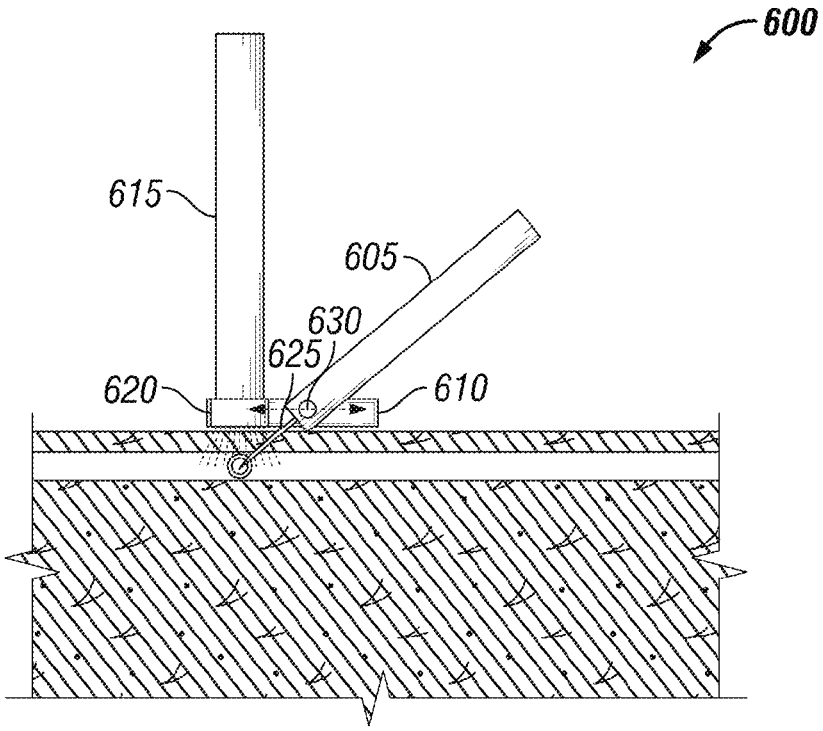


FIG. 17A

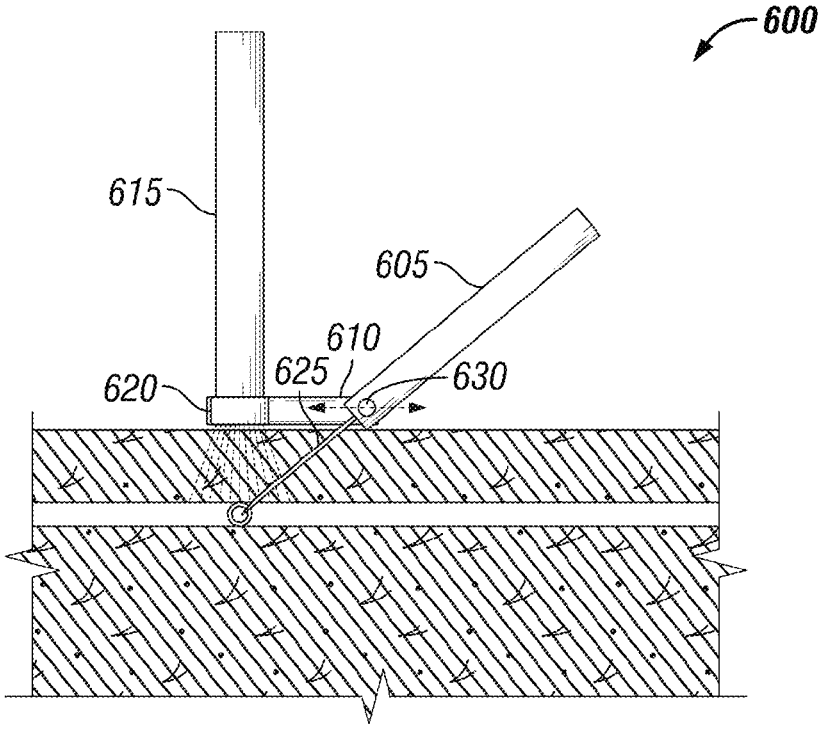


FIG. 17B

# SYSTEMS AND METHODS FOR ACCESSING THE LUMEN OF A VESSEL

## RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 13/080,318, filed on Apr. 5, 2011, and issued as U.S. Pat. No. 8,945,011 on Feb. 3, 2015, which is incorporated herein by reference.

## FIELD OF THE INVENTION

This invention relates to imaging assisted access of the lumen of vessels. More particularly, systems and methods discussed herein are related to the placement of a sheath, needle, and/or guidewire in a vessel.

## BACKGROUND

Medical treatment may require the placement of catheters or the like into a person's body. For example, central venous catheters (also referred to herein as "CVC") are placed in a large vein for a variety of medical purposes. A series of manually performed steps to accomplish CVC placement have remained largely unchanged to date. First, a hollow introducer needle is manually inserted through the skin and placed in the vein. Second, a guide wire is manually inserted through the hollow of the needle into the lumen of the vein. The guide wire is inserted until a portion of the guide wire extends past the end of the needle. In this position, the distal end of the wire is in the central vein and the proximal end is outside the patient's body. The introducer needle, which at this point has the guide wire running through its length, is then removed from the patient by pulling the needle out and over the wire. During removal of the needle, the distal end of the guide wire is undisturbed inside the lumen of the vein. Third, the hollow CVC is placed over the proximal end of the guide wire, and the CVC advanced along the wire, through the skin, the subcutaneous tissues, and into the vein. At its final position, the catheter will have one end in the vein and the other end outside of the body. The guide wire can now be retrieved by pulling the guide wire through the catheter and out of the body, without disturbing the position of the catheter. The catheter can now be used to access to the central venous circulation. This process relies on the medical practitioner to locate the vein and may require several attempts before the CVC is properly placed. Similarly, other medical procedures may require placement of a sheath, needle, and/or guidewire into the lumen of a vessel. Medical practitioners may encounter similar problems when attempting to place a sheath, needle, and/or guidewire into the lumen of a vessel.

More recently, ultrasound has been used to assist in the placement of a CVC in a vein. Ultrasound can be used to locate the venous lumen and provide a visual target. The CVC may be placed manually or a robotic device may be used to place the CVC. Even with ultrasound guidance, a medical practitioner may fail to properly place the CVC. Further, current robotic devices are significantly large, cumbersome, and costly and their use in the placement of CVC is impractical.

## SUMMARY

In an illustrative implementation, an apparatus for accessing the lumen of a vessel is provided. The apparatus includes a reusable handheld device and a disposable cartridge. The reusable handheld device includes a imaging device attachment utilized to secure an image capturing instrument, an arm coupled to the imaging device attachment, and a depth scale coupled to the arm, wherein the depth scale provides a scale indicating an insertion depth. The disposable cartridge attaches to the reusable handheld device. The disposable cartridge includes a sheath, needle or guidewire coupled to the disposable cartridge. The sheath or needle extends to the insertion depth when fully advanced, thereby allowing the sheath, needle, or guidewire to access the lumen of a vessel.

In an illustrative implementation, a method for accessing the lumen of a vessel includes the steps of attaching an image capturing instrument to an imaging device attachment of a reusable handheld device, and attaching a disposable cartridge to a reusable handheld device. The reusable handheld device includes the imaging device attachment for securing an image capturing instrument to the reusable handheld device, an arm coupled to the imaging device attachment, wherein the arm provides a cartridge attachment, and a depth scale coupled to the articulating arm, wherein the depth scale provides a scale indicating an insertion depth of the sheath. The method further includes the steps of placing the reusable handheld device on a desired vessel location, determining a depth of the vessel with an imaging device, and adjusting the insertion depth to the depth determined utilizing the depth scale on the reusable handheld device. The method also includes the steps of advancing a first slider in the disposable cartridge a predetermined distance, wherein the first slider advances a needle or sheath to the depth determined with the imaging device.

In an illustrative implementation, an apparatus for accessing the lumen of a vessel includes a reusable handheld device that provides a body providing an image device attachment and an articulating arm and a depth scale coupled to the arm, wherein the depth scale provides a scale indicating an insertion depth. The apparatus also includes a disposable cartridge attached to the reusable handheld device. The disposable cartridge includes a sheath slidably coupled to the disposable cartridge, a needle slidably coupled to the disposable cartridge, wherein the needle extends to the insertion depth when fully advanced, and a guidewire coupled to the disposable cartridge, wherein the guidewire passes through the center of the needle and the sheath.

The foregoing has outlined rather broadly various features of the present disclosure in order that the detailed description that follows may be better understood. Additional features and advantages of the disclosure will be described hereinafter, which form the subject of the claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present disclosure, and the advantages thereof, reference is now made to the following descriptions to be taken in conjunction with the accompanying drawings describing specific embodiments of the disclosure, wherein:

FIG. **1** is an illustrative implementation of an insertion system;

FIGS. **2**A and **2**B are illustrative implementations of a reusable handheld device with disposable cartridge;

FIGS. **3**A and **3**B are illustrative implementations of a reusable handheld device with disposable cartridge;

FIGS. **4**A and **4**B are illustrative implementations of a disposable cartridge;

FIG. **5** is an illustrative implementation of a back portion of a disposable cartridge;

FIG. **6** is an illustrative implementation of a reusable handheld device and imaging device;

FIG. **7** is an illustrative implementation of a screen overlay;

FIG. **8** is an illustrative implementation of a method for inserting a sheath into a vessel;

FIG. **9** is an illustrative implementation of an alignment cube;

FIG. **10** is an illustrative implementation of a reusable handheld device and image capture instrument placed on top of an alignment cube;

FIG. **11** is an illustrative implementation of a image displayed on an imaging device when a reusable handheld device is placed on top of an alignment cube;

FIG. **12** is an illustrative implementation of an alignment cartridge;

FIGS. **13**A and **13**B are illustrative implementations of a second arrangement for an insertion system;

FIGS. **14**A and **14**B are illustrative implementations of a third arrangement for an insertion system;

FIGS. **15**A and **15**B are illustrative implementations of a fourth arrangement for an insertion system;

FIGS. **16**A and **16**B are illustrative implementations of a fifth arrangement for an insertion system; and

FIGS. **17**A and **17**B are illustrative implementations of a sixth arrangement for an insertion system.

## DETAILED DESCRIPTION

In the following description, certain details are set forth such as specific quantities, concentrations, sizes, etc. so as to provide a thorough understanding of the various embodiments disclosed herein. However, it will be apparent to those of ordinary skill in the art that the present disclosure may be practiced without such specific details. In many cases, details concerning such considerations and the like have been omitted inasmuch as such details are not necessary to obtain a complete understanding of the present disclosure and are within the skills of persons of ordinary skill in the relevant art.

Referring to the drawings in general, it will be understood that the illustrations are for the purpose of describing particular embodiments of the disclosure and are not intended to be limiting thereto. While most of the terms used herein will be recognizable to those of ordinary skill in the art, it should be understood that when not explicitly defined, terms should be interpreted as adopting a meaning presently accepted by those of ordinary skill in the art.

The systems and methods discussed herein are designed to integrate with a commercially available imaging system (e.g. ultrasound system) to provide a medical practitioner with the capability to accurately and reliably accessing the lumen of a vessel located at a depth of 5 mm to 60 mm below the skin surface. For example, the systems and methods discussed herein may be utilized to place a central venous catheter (CVC). While the implementations discussed herein may discuss usage of the systems and methods for starting a CVC, it will be recognized by one of ordinary skill in the art that the scope of the invention is in no way limited to starting a CVC. For example, in other implementations, the system may be utilized to place needle in a vessel; to place a guidewire via a needle placed in a vessel; or to place a sheath via a guidewire that is placed in a vessel via a needle. The systems and methods discussed herein may be utilized in a variety of medical procedures, including, but not limited to: CVC placement, peripherally inserted central catheters, phlebotomy, dialysis access, cardiac catheterization, amniocentesis, cholecystotomy, thoracentesis, paracentesis, and tracheostomy. The insertion system is portable and completely hand operated, requiring no internal or external electrical power source.

FIG. **1** is an illustrative implementation of an insertion system **10**. Insertion system **10** may include a reusable handheld device **15**, alignment cartridge **20**, alignment cube **25**, sterile disposable cartridge **30**, and cover **35**. Reusable handheld device **15** provides for proper alignment of the sheath, needle, and/or guidewire to be inserted into a vessel. Alignment cartridge **20** can be coupled to reusable handheld device **15** and is utilized to perform a check on the alignment of handheld device **15**. Alignment cube **25** is utilized to properly align an imaging system (not shown) coupled to reusable handheld device **15**. Disposable cartridge **30** can be coupled to reusable handheld device **15** and may include a needle, guidewire, dilator, sheath, and other components utilized to place a CVC or the like. Sterile cover **35** may be place on reusable handheld device **15** to prevent contamination or the like. Sterile cover **35** may be placed on or around reusable handheld device **15** and disposed of after usage.

FIGS. **2**A and **2**B are illustrative implementations of a reusable handheld device **15**. For the purposes of illustration and clarity, reusable handheld device **15** is shown without an imaging device and sterile cover. An imaging device, such as an ultrasound, can be coupled to reusable handheld device **15**, but the imaging device is not a part of the reusable handheld device and may be removed when desired. This arrangement allows any suitable brand or type of imaging device to be utilized with handheld device **15**.

Reusable handheld device **15** may include an articulating arm **45**, thumb wheel **50**, cartridge **55**, imaging device attachment **60**, removable lock bar, **65**, slider stop bar **70**, slide stop **75**, and depth adjustment scale **80**. Imaging device attachment **60** is utilized to secure the image capturing instrument of an imaging device to reusable handheld device **15**. For example, an ultrasound transducer may be placed in imaging device attachment **60** and secured to reusable handheld device **15**. Reusable handheld device **15** may provide attachment points to hold and support cartridge **55** on articulating arm **45**. For example, cartridge **55** may be an alignment cartridge or disposable cartridge. Reusable handheld device **15** also includes a thumb wheel **50** that changes the angle of articulating arm **45**.

Removable lock bar **65** locks sliding mechanisms on cartridge **55** in place and may be place onto cartridge **55** to prevent inadvertent advancement or insertion of a needle, catheter, and/or the like. Slider stop bar **70** on cartridge **55** slides in the direction of slide stop **75** when a needle slider or needle is advanced. Slider stop bar **70** impedes advancement of the needle when it comes into contact with slide stop **75**, thereby preventing a medical practitioner from over advancing a needle past a target vessel. Reusable handheld device **15** may also include a depth adjustment scale **80**. When a desired depth is determined using an imaging device, thumb wheel **50** and depth adjustment scale **80** may be utilized to adjust articulating arm **45** to the correct angle for reaching the desired depth.

FIGS. **3**A and **3**B are illustrative implementations of a reusable handheld device **15** and cartridge **55**. When cartridge **55** is mated correctly to reusable handheld device **15**, locking pin **85** protruding from the bottom of cartridge **55** extends through articulating arm **45** of reusable handheld device **15**. Articulating arm **45** provides locking arm **90** for

securing cartridge **55** to reusable handheld device **15**. For example, locking pin **85** may provide a groove that locking arm **90** may be place into for securing cartridge **55**. While locking pin **85** and locking arm **90** are provided in the figure shown, it should be recognized by one of ordinary skill in the art that any suitable securing means may be substituted.

FIGS. **4**A and **4**B are illustrative implementations of a disposable cartridge **100**. Disposable cartridge **100** is sterile to prevent the spread of bacteria, disease, etc. Disposable cartridge **100** will be disposed after a single use. Disposable cartridge **100** may include lock bar **105**, sheath slider **110**, needle slider **115**, guidewire **120**, cartridge base **125**, span brace **130**, guide slot **135**, and attachment tab **140**. Attachment tab **140** is an L-shaped tab that may be secured to the reusable handheld device. A locking pin and attachment tab **140** mate disposable cartridge **100** to the reusable handheld device.

Lock bar **105** is designed to secure the sheath slider **110**, needle slider **115**, and/or associated medical components in a desired position to prevent undesired movement before lock bar **105** is removed. For example, during shipping, before attachment to the reusable handheld device, and/or prior to use it is desirable to prevent a sharp needle and sheath from protruding from disposable cartridge **100**. However, when disposable cartridge **100** is attached to a reusable handheld device that is ready for use, lock bar **105** may be removed to allow sheath slider **110**, needle slider **115**, and associated medical components to be freely advanced and retracted.

Disposable cartridge **100** may also include a sterile needle **145**, sheath **150**, and guidewire **120**. Guidewire **120** runs inside a track located in the wall of disposable cartridge **100** and continues through the inside of needle **145**. Needle **145** is positioned in the center of sheath **150** and may slide into and out of sheath **150**. In some implementations, a dilator may be provide in between needle **145** and sheath **150** to minimize or prevent bending of needle **145**. There are two sliders in disposable cartridge **100**. Needle slider **115** controls the advancement and retraction of the needle **145**. Needle slider **115** is coupled to slider stop bar **70** shown in FIG. **2**B. As needle slider **115** is advanced, slider stop bar **70** is also advanced. The depth the tip of needle **145** extends from reusable handheld device **15** is determined by rotating thumb wheel **50** until depth adjustment scale **80** on reusable handheld device **15** shows the desired depth. Pushing needle slider **115**, toward a patient until the slider stop bar **70** hits slide stop **75**, causes needle **145** to extend out from disposable cartridge **100** and into a patient to the desired depth. Moving needle slider **115** away from the patient until it hits the proximal end of a slider track fully retracts needle **145** into disposable cartridge **100**.

Sheath slider **110** controls the advancement and retraction of sheath **150**. Because sheath slider **110** is placed in front of needle slider **115**, advancing needle slider **115** also causes sheath slider **110** to advance. However, retracting of needle slider **115** does not cause sheath slider **110** to retract. Additionally, sheath slider **110** is not coupled to slider stop bar **70**, which allows sheath slider **110** to be advanced further than needle slider **115**. Sheath **150** has a larger diameter than needle **145** and is placed over the needle. Guidewire **120** passes through needle **145**. Pushing sheath slider **110** toward the patient advances sheath **150** over needle **145** tracking over guidewire **120** and into a target vessel. Guide slot **135** supports needle **145** during insertion. Guide slot **135** does not completely surround needle **145** or sheath **150** so as to provide an exit point for the sheath **150** after it has been inserted into the patient. Disposable cartridge **100** may provide an opening below span brace **130** that allows sheath **150** to be easily removal of from disposable cartridge **100**.

FIG. **5** is an illustrative implementation of a back portion of a disposable cartridge **100**. Both the needle and sheath sliders run along slider track **155**. A seal **160** may be place on slider track **155** to maintain a seal around a slider as it moves along slider track **155**. Slider track plate **165** is place over seal **160** and may be secured to disposable cartridge **100**. Disposable cartridge **100** may also include a sterile cover attached to the cartridge via slider track plate **165** or any other suitable attachment point. The cover can be positioned over an image capturing instrument and the reusable handheld device when disposable cartridge **100** is attached to the reusable handheld device **15**. This sterile cover is not shown in the figures above to provide an unobstructed view of the disposable cartridge features. Guidewire **120** is advanced by grasping the guidewire with the forefinger and thumb and moving it in a proximal direction. This will cause guidewire **120** to advance in the distal direction through the needle into the patient's vessel. During advancement of guidewire **120**, the operator may view the advancement of guidewire **120** on a display of the imaging device. Guidewire **120** may also be advanced by grasping the guidewire proximal to the needle hub and moving the guidewire through the needle into the patient's vessel.

FIG. **6** is an illustrative implementation of a reusable handheld device **15** and imaging device **170**. Imaging device **170** may include an image capturing instrument **175** that may be secured in imaging device attachment **60** of reusable handheld device **15**. Image capturing instrument **175** may send and/or received signals utilized to generate images. Imaging device **170** receives data from image capturing instrument **175** and shows the generated images on display **182**. For example, a commercially available ultrasound imaging device may be utilized and the ultrasound transducer may be secured in imaging device attachment **60** of the reusable handheld device **15**. Screen overlay **180** is a transparent adhesive film that may include a vertical dashed line in the center and tick marks on each side. Screen overlay **180** is designed to fit on and adhere to a display **182** of imaging device **170**. Screen overlay **180** provides an operational reference for use of insertion system **10**.

FIG. **7** is an illustrative implementation of a screen overlay **180**. Screen overlay **180** may be a clear, thin, plastic sheet with low tack adhesive that can be affixed to a display **182** of imaging device **170**. Screen overlay **180** may provide a vertical dashed center line and tick marks on each side that provides a visual reference aid to the user. Screen overlay **180** and imaging device **170** allow the medical practitioner to accurately locate a vessel and determine the depth of the vessel. The medical practitioner may then set insertion system **10** to the measured depth via hand control of thumb wheel **50** and insert the needle **145**, sheath **150**, and/or guidewire **120** via hand control of the needle slider **115**, sheath slider **110**, and/or guidewire **120**. It should be noted that an image capturing instrument **175** of the imaging device **170** connects to the reusable handheld device, but imaging device **170** is not part of the insertion system. Since medical facilities may already have a suitable imaging device, utilizing an existing imaging device, rather than incorporating the imaging device, reduces cost. This also allows the sheath insertion methods and systems discussed herein to easily be adapted for use with a variety of different types and/or brands of imaging devices. Imaging devices that are suitable for use with the insertion systems discussed

herein will preferably be capable of imaging and measuring depths of approximately 5 mm to 60 mm.

FIG. **8** is an illustrative implementation of a method for inserting a sheath into a vessel. While the following provides a description of inserting a sheath into a vessel, it will be recognized by one of ordinary skill in the art that the device is suitable for a variety of medical procedures involving the insertion of a sheath, needle, and/or guidewire into the lumen of a vessel. The scope of the claims is in no way limited to inserting a sheath into a vessel, except where expressly stated in the claims. For example, in other implementations, the insertion system may simply be utilized to place a needle in the lumen of a vessel or to place a guidewire in the lumen of a vessel with the aid of a needle. To prepare insertion system **10** for use, the user will integrate the reusable handheld device **15** with imaging device **170** in step S**100** by placing image capturing instrument **175** in imaging device attachment **60** and securing it with the thumb screws or the like. In step S**105** the alignment of the reusable handheld device **15** may be checked with an alignment cartridge **20**. In step S**110** the alignment of the imaging device **170** can be check with an alignment cube **25**. During this alignment, screen overlay **180** may be placed on the display of the imaging device **170**. Aligning the reusable handheld device **15** and imaging device **170** with an alignment cartridge **20** and alignment cube **25** are discussed in further detail below. Note that the alignment steps S**105** and S**110** are optional steps that are performed for best results. However, in the case that alignment checks have been previously performed in the same day or recently, it may not be necessary to perform the alignment checks. Additionally, many of the steps for the method discussed herein may be performed in a different sequence than shown or omitted. The scope of methods for inserting a sheath into a vessel is in no way limited to the particular methods illustrated herein. One of ordinary skill in the art will recognize a variety of potential variations in the sequence and particular steps performed.

Disposable cartridge **100** can be attached to the articulating arm **45** of reusable handheld device **15** in step S**115**. Next, reusable handheld device **15** can be placed on a desired vessel location to find a target vessel in step S**120**. The display of the imaging device will provide an image of desired location. In step S**125**, the operator may adjust reusable handheld device so the target vessel is centered on the vertical dotted line of screen overlay **180**. The operator may then utilize the imaging device **170** to determine the target depth of the vessel in step S**130**. The target depth indicates the distance from the top surface (or skin of the patient) to the center of the vessel. When the target depth of the vessel is determined, the operator can adjust the thumb wheel **50** to modify the insertion depth of the needle utilizing the depth adjustment scale **80** on reusable handheld device **15** in step S**135**. Once the operator has modified the insertion depth to the target depth, the needle slider **115** can be advanced to insert the needle **145** into the patient in step S**140**.

Once the needle **145** is fully advanced, the operator can advance the guidewire **120** through the needle into the target vessel in step S**145**. Next, sheath slider **110** can be advanced to move sheath **150** along guidewire **120** into the target vessel in step S**150**. Now that the sheath **150** is in the target vessel, the needle slider can be retracted in step S**150**. Finally, in step S**160**, sheath **150** can be removed from reusable handheld device **15**, thereby completing placement of the sheath in the target vessel.

Two alignment tasks may be performed to check the alignment of the reusable handheld device **15**. The first step in the alignment process is performed as part of the preparation procedure to ensure correct positioning of the image capturing instrument **175** in the imaging device attachment **60**. The second step in the alignment check is performed to confirm that the slide stop **75** on the reusable handheld device **15** is in the correct position. Both alignment tasks can be performed in a non-sterile or sterile environment.

FIG. **9** is an illustrative implementation of an alignment cube **200**. Alignment cube **200** enables the user to perform alignment tasks. Top lid **205** of alignment cube **200** provides a needle insertion port **210**, alignment guides **215**, and image capturing window **220**. Needle insertion port **210** provides an entry point for the stylet **320** to enter alignment cube **200**. Alignment guides **215** receive the imaging device attachment **60** of the reusable handheld device **15** and serve to properly align the reusable handheld device **15** to alignment cube **200**. Image capturing window **220** provides an opening for the image capturing instrument **175** of the imaging device. Image capturing window **220** is directly above the shallow vessel target (X-Axis) **225** and deep vessel target (X-Axis) **227** in alignment cube **200**.

The shallow vessel target **225** is positioned at a depth of 30 mm and the deep vessel target **227** is positioned at a depth of 60 mm. The shallow vessel target **225** and deep vessel target **227** are arranged perpendicular to the image capturing window **220** and horizontal to the top lid **205**, defining the x-axis of the alignment cube **200**. Both the shallow vessel target **225** and deep vessel target **227** in the alignment cube **200** includes a premeasured and marked target center point. In particular, the target center points are indicated by wire structures intersecting shallow vessel target **225** and deep vessel target **227**. Target wire (Y Axis) **230** is arranged vertically or along the y-axis in alignment cube **200**. Two target wires (Z-Axis) **235** are arranged perpendicular to the shallow vessel target **225** and deep vessel target **227** along the z-axis in alignment cube **200**. Target wire (Z-Axis) **235** are perpendicular to shallow vessel target **225**, deep vessel target **227** and target wire (Y-Axis) **230**. The shallow vessel target **225** at a depth of 30 mm may include a stylet window **240** that allows the stylet to pass through to the deep target vessel **227**. This stylet window **240** allows the needle/stylet to reach deep vessel target **227** at a depth of 60 mm. Alignment cube **200** may include several viewing windows **245**, or the sides of the cube may be made of a transparent material, to allow a user to view the alignment process of the reusable handheld device **15**. Alignment cube **200** and the shallow vessel target **225** and deep vessel target **227** can be filled with water by the user to accommodate the imaging signal.

FIG. **10** is an illustrative implementation of a reusable handheld device **15** placed on top of an alignment cube **200**. The first step in the alignment process is to attach the image capturing instrument **175** to the reusable handheld device **15** and secure it in place with the thumbscrews **250**. Note that image capturing instrument **175** and reusable handheld device **15** should be cleaned and disinfected prior to the first alignment check. With the image capturing instrument **175** attached, the user can power on the imaging device. After filling the alignment cube **200** with water, the reusable handheld device **15** may be placed on top of the alignment cube **200**. Image capturing instrument **175** is repositioned in the imaging device attachment **60** to make sure that it is positioned correctly and properly aligned.

In order to properly align image capturing instrument **175**, target vessels **225**, **227** and target wires **230**, **235** should be

properly aligned on the display of the imaging device. Once target vessels **225**, **227** and target wires **230**, **235** are properly aligned on the display, screen overlay **180** should be positioned in alignment with target vessels **225**, **227** and target wires **230**, **235** displayed on imaging device **170**. For example, screen overlay **180** may be position as shown in FIG. **11**. When image capturing instrument **175** and screen overlay **180** are properly aligned, the vertical dashed centerline of screen overlay **180** corresponds to a plane of the needle and sheath.

FIG. **11** is an illustrative implementation of a image displayed on an imaging device when a reusable handheld device **15** is placed on top of an alignment cube **200**. When image capturing instrument **175** is properly aligned, the image resulting from placing reusable handheld device **15** on top of an alignment cube **200** should resemble FIG. **11**. The ultrasound system display should show two circles **260**, **265** aligned vertically in the center of the screen representing the shallow target vessel **225** and deep target vessel **227** at 30 mm and 60 mm, respectively, in alignment cube **200**. Each of the circles **260**, **265** will have a bright horizontal line **270** through the center. Vessel targets **225**, **227** have target wires **235** travelling along the z-axis of alignment cube **200** passing through them. Target wires **235** are represented by horizontal lines **270** passing though the top circle **260** and bottom circle **265**. During the alignment check, the user can rotate the image capturing instrument **175** about the x-axis until horizontal lines **270** in the 30 mm and 60 mm vessel simulation are horizontal. Horizontal tick marks **280** may be provided by screen overlay **180** to help the operator determine a horizontal position. The user may then pitch the image capturing instrument **175** about the z-axis until the circles **260**, **265** are clear and a small white circle **255** representing target wire **230** appears at the top center of the 30 mm vessel simulation image circle **260**.

Holding that position, the user or an assistant can hand tighten thumb screws **250** on the imaging device attachment **60**. Screen overlay **180** should be placed on the screen so that the center line dissects circles **260**,**265** through small white circle **255** at the top center and horizontal lines **270** looks horizontal when compared to the side tick marks. The final check of the alignment process is to use the depth measuring capability of the ultrasound system to measure the depth of the Z-axis vessel simulation wire at 60 mm. This is done by placing a mark **275** on the top of the display and another mark **275** (vertically aligned) on the image of the Z-axis of the 60 mm vessel simulation. Measured distance **285** computed by the imaging device should match the known depth of the wire i.e. 60 mm. Similarly, a check may be performed on the vessel target at 30 mm.

The purpose of the second alignment check procedure is to ensure that the mechanical structure and sliders have not moved out of position due to misuse or damage. FIG. **12** an illustrative implementation of an alignment cartridge **300**. Alignment cartridge **300** can be used to perform the alignment check procedure. Alignment cartridge **300** has the same interfaces and attachment points as the disposable cartridge, but does not contain any medical components. Similar to the disposable cartridge, attachment tab **305** and locking pin **310** are utilized to attach alignment cartridge **300** to the reusable handheld device. Alignment cartridge **300** provides a stylet slider **315** attached to a stylet **320** that is the same length as the needle in the sterile disposable cartridge. Cartridge base **325** provides an opening that receives stylet slider **315** and allows stylet slider **315** to be advanced and retracted.

The user begins the procedure in a non-sterile or sterile environment by placing the image capturing instrument **175** in imaging device attachment **60** and securing it in place with the thumb screws **250**. With image capturing instrument **175** securely in place, the user attaches the alignment cartridge **300** to the reusable handheld device **15**. After filling the alignment cube **200** with water, the user can follow the previously discussed alignment steps discussed above, if necessary, to align the position of the image capturing instrument if necessary. However, note that a screen overlay is not required to perform the alignment check procedure.

When the image capturing alignment or first alignment check is successfully completed, the user can set the thumb wheel **50** on the reusable handheld device **15** to a depth of 30 mm and actuate stylet slider **315** on alignment cartridge **300**. When the slider stop bar **70** hits the slide stop **75**, the distal end of stylet **320** should touch the intersection point at 30 mm between z-axis wire **235** and y-axis wire **230**. Visual confirmation of this is made by looking through the viewing windows on the sides of the alignment cube. The user can then repeat this procedure for the intersection point at 60 mm between the z-axis wire **235** and y-axis wire **230**. If visual confirmation indicates that the stylet does not touch the intersection points of the wires at 30 mm or 60 mm, the reusable handheld device is recalibrated and adjusted for proper alignment.

An example of a method for inserting a sheath into a vessel is discussed in detail below. In particular, the method discussed utilizes an ultrasound imaging device with insertion system **10**. Initially, first and second alignment checks are performed with alignment cube **200** and alignment cartridge **300** as described previously. With the alignment checks complete, the insertion system is ready for use on the patient. Preparation may include, if necessary, positioning the patient, disinfecting the procedure site, draping the procedure site, administering anesthesia, and the like. The final patient preparation step is the application of sterile ultrasound gel to the procedure site. With patient preparation complete, the user applies the sterile ultrasound gel to the image capturing instrument **175** and attaches the sterile disposable cartridge **100** to reusable handheld device **15**. With gel correctly applied to the image capturing instrument **175** and sterile disposable cartridge **100** attached, the user positions sterile cover **35** over reusable handheld device **15** and image capturing instrument **175**. With the cover correctly positioned, the user can place reusable handheld device **15** on the patient at the procedure site and begin to receive ultrasound images of the patient's vessel(s) displayed on the display. The ultrasound imaging display, with screen overlay **180**, allows the user to adjust reusable handheld device **15** until the desired target vessel is centered on the vertical dotted line on screen overlay **180** or the target plane of needle **145** and sheath **150**. The user can use the distance measuring capability of the ultrasound imaging device to measure the depth to the center of the target vessel. Additionally, the user can use the distance measuring capability of the ultrasound imaging device to measure the semi-major axis and semi-minor axis of the vessel image to determine the diameter of the target vessel. The depth of the vessel should be between 5 mm and 60 mm, and the diameter of the vessel should be at least 4 mm in diameter. If the depth or diameter is inappropriate, the user should select a different place along the vessel where the depth and diameter are satisfactory. To set reusable handheld device **15** to the depth value obtained from the depth measurement, the user actuates the thumb wheel **50** to the targeted depth. With

depth setting on the reusable handheld device **15** achieved, the user may then actuate needle **145** by moving the needle slider **115** of disposable cartridge **100** toward the patient. This inserts needle/dilator **145** into the patient and places the needle in the center of the target vessel. With needle/dilator **145** fully advanced into the patient's vessel, the user can actuate guidewire **120** by using his/her index finger to press against and advance guidewire **120** toward the patient. Using this motion, the user can advance the guidewire **120**, through the proximal end of needle **145** to desired length beyond the distal end of the needle. The user can evaluate the placement of the guidewire via the ultrasound image display **182**.

With guidewire **120** fully advanced into the patient's vessel, the user can actuate sheath slider **110** on the disposable cartridge toward the patient until sheath slider **110** reaches the end of slider track **155**. The guidewire **120**, needle **145**, and sheath **150** are now resident in the target vessel. The user can fully retract needle **145** by moving needle slider **115** away from the patient, while maintaining sheath slider **110** and sheath **150** in the fully advanced position. This will retract needle **145** completely back into disposable cartridge **100** and out of sheath **150**.

With sheath insertion complete, the user can remove sheath **150** from the guide slot **135**. While holding sheath **150** and guidewire **120** in place, the user may remove reusable handheld device **15** from the patient. As reusable handheld device **15** is moved away from the patient, the proximal end of guidewire **120** slides through needle **145** and separates from disposable cartridge **100**. Disposable cartridge **100** is then removed from reusable handheld device **15** and disposed. Image capturing instrument **175** and reusable handheld device **15** may then be separated from each other, cleaned, disinfected, and stored.

FIGS. **13**A and **13**B are illustrative implementations of a second arrangement for an insertion system **400**. In insertion system **400**, cartridge **405** is fixed at a predetermine angle. While cartridge **405** is shown independently attached to boom **410**, in other implementations, cartridge **405** may be secured to fixed arm in a similar manner as to the articulating arm **45** shown in FIGS. **3**A and **3**B. Cartridge **405** may be coupled to adjustable boom **410**, which may be adjusted vertically to achieve different target depths. Boom **410** is coupled to transducer arm **415**. Transducer arm **415** may provide a depth scale that indicates the needle depths of the range of heights for boom **410**. Transducer arm **415** provides an attachment for transducer **420**. Needle **425** extends to a fixed predetermined length.

FIGS. **14**A and **14**B are illustrative implementations of a third arrangement for an insertion system **450**. In insertion system **450**, cartridge **455** has a variable angle in relation to boom **460**. While cartridge **455** is shown independently attached to boom **460**, in other implementations, cartridge **455** may be secured to fixed arm in a similar manner as to the articulating arm **45** shown in FIGS. **3**A and **3**B. In contrast to the previous implementation, boom **460** is a fixed height. Boom **460** is coupled to transducer arm **465**, which provides an attachment for transducer **470**. Needle **475** is a variable length needle. As the angle of cartridge **455** increase, the depth of insertion increases. The angle of cartridge **455** and length of needle **475** are adjusted to achieve a desired target depth. A depth scale (not shown) for insertion system **450** takes into account the angle of cartridge **455**. The depth scale may indicate the depth of needle **475** based on the angle of cartridge **455** and the amount needle **475** has been extended.

FIGS. **15**A and **15**B are illustrative implementations of a fourth arrangement for an insertion system **500**. In insertion system **500**, cartridge **505** has a variable angle in relation to boom **510**. While cartridge **505** is shown independently attached to boom **510**, in other implementations, cartridge **505** may be secured to fixed arm in a similar manner as to the articulating arm **45** shown in FIGS. **3**A and **3**B. Boom **510** is fixed near the bottom of transducer arm **515**. Transducer arm **515** provides an attachment for transducer **520**. Needle **525** is a variable length needle. As in the previous implementation, the angle of cartridge **505** and length of needle **525** are adjusted to achieve a desired target depth. A depth scale (not shown) for insertion system **500** takes into account the angle of cartridge **505**. The depth scale may indicate the depth of needle **525** based on the angle of cartridge **505** and the amount needle **525** has been extended.

FIGS. **16**A and **16**B are illustrative implementations of a fifth arrangement for an insertion system **550**. In insertion system **550**, cartridge **555** has a variable angle in relation to boom **560**. While cartridge **555** is shown independently attached to boom **560**, in other implementations, cartridge **555** may be secured to fixed arm in a similar manner as to the articulating arm **45** shown in FIGS. **3**A and **3**B. Boom **560** is fixed near the bottom of transducer arm **565**. Transducer arm **565** provides an attachment for transducer **570**. Needle **575** is a fixed length needle. In contrast to the previous implementations, cartridge **555** has a variable pivot point **580** that can be moved along boom **560**. The angle of cartridge **555** and variable pivot point **580** are adjusted to achieve a desired target depth. A depth scale (not shown) for insertion system **550** takes into account the angle of cartridge **555** and the variable pivot point **580**.

FIGS. **17**A and **17**B are illustrative implementations of a sixth arrangement for an insertion system **600**. In insertion system **600**, cartridge **605** has a fixed angle in relation to boom **610**. While cartridge **605** is shown independently attached to boom **610**, in other implementations, cartridge **605** may be secured to fixed arm in a similar manner as to the articulating arm **45** shown in FIGS. **3**A and **3**B. Boom **610** is fixed near the bottom of transducer arm **615**. Transducer arm **615** provides an attachment for transducer **620**. Needle **625** is a variable length needle. Cartridge **605** has a variable pivot point **630** that can be moved along boom **610**. The variable pivot point **630** of cartridge **605** and length of needle **625** are adjusted to achieve a desired target depth. A depth scale (not shown) for insertion system **600** takes into account the a variable pivot point **630** and the amount needle **625** has been extended.

From the variety of arrangements discussed above, it should be noted that various arrangements may be also be suitable. For example, any suitable combination of a fixed/variable boom elevation, fixed/variable angle cartridge, fixed/variable needle length, and/or fixed/variable pivot point may be utilized.

Embodiments described herein are included to demonstrate particular aspects of the present disclosure. It should be appreciated by those of skill in the art that the embodiments described herein merely represent exemplary embodiments of the disclosure. Those of ordinary skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments described and still obtain a like or similar result without departing from the spirit and scope of the present disclosure. From the foregoing description, one of ordinary skill in the art can easily ascertain the essential characteristics of this disclosure, and without departing from the spirit and scope thereof, can make various changes and modifications to

adapt the disclosure to various usages and conditions. The embodiments described hereinabove are meant to be illustrative only and should not be taken as limiting of the scope of the disclosure, which is defined in the following claims.

From the foregoing description, one of ordinary skill in the art can easily ascertain the essential characteristics of this disclosure, and without departing from the spirit and scope thereof, can make various changes and modifications to adapt the disclosure to various usages and conditions. The embodiments described hereinabove are meant to be illustrative only and should not be taken as limiting of the scope of the disclosure, which is defined in the following claims.

What is claimed is the following:

**1**. A method for accessing a lumen of a vessel, the method comprising the steps of:

attaching an image capturing instrument of an imaging device to an imaging device attachment of a reusable handheld device;

attaching a disposable cartridge to the reusable handheld device, wherein the disposable cartridge comprises,

a needle or sheath housed in the disposable cartridge, and

a first slider slidably attached to the disposable cartridge, wherein the first slider is coupled to the needle or sheath, and

the reusable handheld device comprises,

the imaging device attachment for securing the image capturing instrument to the reusable handheld device,

an arm coupled to the imaging device attachment, wherein the arm provides a cartridge attachment, and

a depth scale providing a scale indicating an insertion depth of a needle or sheath; placing the reusable handheld device on a desired vessel location; determining a depth of the vessel with the imaging device;

adjusting the insertion depth on the depth scale to the depth determined with the imagine device; and

advancing the first slider in the disposable cartridge a predetermined distance, wherein the first slider advances the needle or sheath to the depth determined with the imaging device;

wherein the reusable handheld device further comprises a slider stop bar coupled to a first slider, wherein the slider stop bar advances with the first slider; and

a slide stop attached to the reusable handheld device that is positioned in a sliding direction of the slider stop bar to impede advancement of the slider stop bar when it comes into contact with the slide stop, wherein the first slider is advance a predetermined distance until the slider stop bar contacts the slide stop to advance the needle or sheath to the depth determined with the imaging device.

**2**. The method of claim **1**, wherein the image capturing instrument is an ultrasound transducer and the imaging device is an ultrasound imaging device.

**3**. The method of claim **1**, wherein the insertion depth is adjusted by rotating a thumb wheel coupled to the arm of the reusable handheld device.

**4**. The method of claim **1**, wherein the depth scale is a member coupled to the arm of the reusable handheld device and indicates the insertion depth, and a thumb wheel adjusts the arm along the depth scale to change the insertion depth.

**5**. The method of claim **1**, further comprising the step of:

advancing a second slider in the disposable cartridge, wherein the second slider advances the sheath to the depth determined with the imaging device;

advancing a guidewire through the sheath into the vessel; and

retracting the first and second slider into the disposable cartridge.

**6**. The method of claim **1**, further comprising the step of checking a first alignment of the reusable handheld device, wherein the first alignment is checked with an alignment cartridge providing a stylet and a stylet slider.

**7**. The method of claim **1**, further comprising the step of checking a second alignment of the image capturing instrument, wherein the second alignment is checked with an alignment cube providing at least one target vessel.

**8**. The method of claim **7**, wherein the alignment cube provides a first target wire and a second target wire, wherein the first target wire is arranged vertically through a center of the target vessel in the alignment cube, and the second target wire is arranged horizontally through the center of the target vessel and the second target wire intersects the first target wire.

**9**. The method of claim **8**, further comprises the step of adjusting the image capturing instrument to a desired position in which the second target wire is displayed as a horizontal line on a display of the imaging device; and

securing the image capturing instrument in the desired position on the reusable handheld device.

**10**. The method of claim **1**, further comprising the step of placing a screen overlay on a display of the imaging device.

**11**. An apparatus for accessing a lumen of a vessel, the apparatus comprising:

a reusable handheld device, wherein the reusable handheld device comprises,

an imaging device attachment, wherein the imaging device attachment is utilized to secure an image capturing instrument of an imaging device to the reusable handheld device,

an arm coupled to the imaging device attachment, wherein the arm provides a cartridge attachment,

a slider stop bar coupled to a first slider, wherein the slider stop bar advances with the first slider, and

a slide stop attached to the reusable handheld device that is positioned in a sliding direction of the slider stop bar to impede advancement of the slider stop bar when it comes into contact with the slide stop; and

a disposable cartridge attached to the arm of the reusable handheld device, wherein the disposable cartridge houses a needle or sheath that advances to an insertion depth to access the lumen of the vessel, and the disposable cartridge comprises

a slider track receiving the first slider, and

the first slider slidably attached to the slider track of the disposable cartridge, wherein the first slider is coupled to the needle or sheath, and

when the first slider is advanced a predetermined amount, the slider stop bar contacts the slide stop prior to contacting an end of the slider track to impede advancement, and a tip of the needle or sheath is at the insertion depth.

**12**. The apparatus of claim **11**, wherein the disposable cartridge further comprises a second slider slidably attached to the slider track of the disposable cartridge, wherein the second slider is coupled to the sheath in the disposable cartridge.

**13**. The apparatus of claim **11**, wherein the reusable handheld device further comprises a thumb wheel coupled to the arm, wherein the thumb wheel is rotatable to adjust an angle of the arm and the insertion depth of the needle or sheath.

**14**. The apparatus of claim **11**, wherein a body of the reusable handheld device further comprises a depth scale

providing a scale indicating the insertion depth, wherein the depth scale is a member coupled to the arm of the reusable handheld device.

**15**. The apparatus of claim **11**, wherein the disposable cartridge further comprises a lock bar that prevents movement of the first slider.

**16**. The apparatus of claim **11**, further comprising an alignment cartridge with a stylet and a stylet slider, wherein the alignment cartridge is attached to the arm of the reusable handheld device in place of the disposable cartridge, and the alignment cartridge is utilized to check a first alignment of the reusable handheld device.

**17**. The apparatus of claim **16**, further comprising an alignment cube with at least one target vessel, wherein the reusable handheld device is placed on the alignment cube to check a second alignment of the image capturing instrument secured to the reusable handheld device.

**18**. The apparatus of claim **17**, wherein the alignment cube provides a first target wire and a second target wire, wherein the first target wire is arranged vertically through a center of the target vessel in the alignment cube, and the second target wire is arranged horizontally through the center of the target vessel and the second target wire intersects the first target wire.

**19**. The apparatus of claim **11**, further comprising a screen overlay with a vertical line provided in the center of the screen overlay.

**20**. An apparatus for accessing a lumen of a vessel, the apparatus comprising:

a reusable handheld device, wherein the reusable handheld device comprises,

an imaging device attachment, wherein the imaging device attachment is utilized to secure an image capturing instrument of an imaging device to the reusable handheld device,

an arm coupled to the imaging device attachment, wherein the arm provides a cartridge attachment, and

a depth scale providing a scale indicating an insertion depth of a needle or sheath; and

a disposable cartridge attached to the arm of the reusable handheld device, wherein the disposable cartridge houses a needle or sheath that advances to an insertion depth to access the lumen of the vessel, and the disposable cartridge comprises

a slider track receiving a first slider, and

the first slider slidably attached to the slider track of the disposable cartridge, wherein the first slider is coupled to the needle or sheath;

wherein the reusable handheld device further comprises a slider stop bar coupled to the first slider, wherein the slider stop bar advances with the first slider, and

a slide stop attached to the reusable handheld device that is positioned in a sliding direction of the slider stop bar to impede advancement of the slider stop bar when it comes into contact with the slide stop

when the first slider is advanced a redetermined amount the slider stop bar contacts the slide stop prior to contacting an end of the slider track to impede advancement, and a tip of the needle or sheath is at the insertion depth.

**21**. The apparatus of claim **20**, wherein the disposable cartridge further comprises a second slider slidably attached to the slider track of the disposable cartridge, wherein the second slider is coupled to the sheath in the disposable cartridge.

**22**. The apparatus of claim **20**, wherein the reusable handheld device further comprises a thumb wheel coupled to the arm, wherein the thumb wheel is rotatable to adjust an angle of the arm and the insertion depth of the needle or sheath.

**23**. The apparatus of claim **20**, wherein the depth scale is a member coupled to the arm of the reusable handheld device and indicates the insertion depth, and a thumb wheel adjusts the arm along the depth scale to change the insertion depth.

**24**. The apparatus of claim **20**, wherein the disposable cartridge further comprises a lock bar that prevents movement of the first slider.

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